Washington State TB Guidelines

Please Note:

The American Thoracic Society (ATS) and the Centers for Disease Control and Prevention (CDC) recommend that the 2-month regimen of Rifampin and Pyrazinamide should not be offered to persons for the treatment of latent TB infection, for either HIV-negative or HIV-infected persons.

Snohomish Health District
TB Control Program

Subject: Protocol and Standing Orders for Evaluation and Management of Tuberculosis Infection and Disease	Effective date: March 30, 2004
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Author: Christopher Spitters, MD/MPH TB Medical Consultant	Approved by:_____ Ward Hinds, MD/MPH Health Officer Date approved:

Purpose: To provide SHD clinical staff with guidelines for evaluating and managing patients who present for tuberculosis (TB) screening or with a clinical presentation suspicious for active TB. This document is intended to complement pursuit of consultation from the TB medical consultant/control officer where appropriate.

Protocol:

I. TB Skin Testing

- Candidates for TB Screening through SHD
  - ♦ Recent close contacts of active cases
  - ♦ Persons known to have radiographic evidence suggestive of old, healed TB
  - ♦ Persons identified by immigration screening to have abnormal chest films suggestive of old or active TB (Class A/B)
  - ♦ Refugees
  - ♦ Other immigrants who have resided in the US for 5 years or less
  - ♦ Persons who have traveled to high-prevalence regions for ≥6 months during the preceding 5 years
  - ♦ Homeless persons
  - ♦ Persons who have injected illicit drugs
  - ♦ Persons seeking treatment for substance abuse
  - ♦ HIV infected persons
  - ♦ Organ transplant recipients
  - ♦ Persons with medical conditions that predispose to developing active disease if infected
    - ▪ Diabetes mellitus (especially insulin dependent or poorly controlled)

- Chronic steroid therapy (e.g., equivalent of prednisone 15-20 mg per day for greater than one month)
- Other immunosuppression (acquired or medically induced)
- Cancer of the head/neck, lung, hematologic system (e.g., leukemia) or reticuloendothelial system (e.g., lymphoma)
- End-stage renal disease (i.e., chronic hemodialysis and transplant candidates)
- Malabsorptive states (e.g., small bowel resection, intestinal bypass)
- Less than 90% ideal body weight-for-height
- Silicosis
- Residents and employees of high-risk congregate settings (e.g., correctional facilities, homeless shelters, inpatient facilities)

Note: Employees of high-risk congregate settings who do not meet any of the other risk criteria set forth above may be triaged to their employer's occupational health care provider or to primary care when screening resources are limited.

- Transient clients who are clinically well and are neither contacts, HIV-infected, refugees nor class A/B immigrants may have TB screening deferred until arrival in their anticipated community of residence if they do not plan to reside in this jurisdiction for a period adequate to complete screening and treatment. More specifically…
  - Such clients planning to move out of the United States should be screened only if their current stay in the United States will exceed nine months.
  - Such clients planning to move out of Washington (but to remain in the United States) should be screened only if their current stay in Washington will exceed six months.
  - Such clients planning to move out of Snohomish County (but remain in Washington) should be screened only if their current stay in Snohomish County will exceed three months.

- TB Screening in Pregnancy
  - Pregnant women should not be screened unless the managing health care provider plans to treat them during pregnancy, if they are indeed found to have latent TB. Consequently, screening during pregnancy should generally be limited to women who meet one or more of the following criteria:
    - Contact with a smear positive case within the preceding 24 months
    - HIV infection
    - Other medical conditions (listed above) that increase the risk for developing active TB
    - Known radiographic abnormalities consistent with prior active TB (including class A/B immigrants)
    - Refugees and immigrants who have arrived within the preceding 24 months from high-risk regions of the globe
    - Employment in a high-risk occupational setting that is known to serve patients with active TB
  - Pregnant women who lack all of the factors described immediately above may have skin testing deferred until the post-partum medical evaluation.

- In the event such screening does occur in such a "lower-priority" pregnant woman and she is found to have a positive skin test (e.g., 10+mm), a posteroanterior chest radiograph (with abdominal shield) should be obtained to assess for evidence of active pulmonary disease. If the radiograph is normal or shows only calcified granulomata, treatment should be deferred until 4-6 weeks after delivery. At that time a repeat chest radiograph should be obtained and reviewed prior to starting treatment for latent TB.

- Standing Orders for Administration and Interpretation of TB Skin Tests:
  - Administer Purified Protein Derivative (PPD) 5 units (0.1 ml) intradermally in the left lateral forearm.
  - Alternative sites include the right lateral forearm or the posterior aspect of either trapezius muscle.
  - Skin tests should not be administered on a day that will cause the 48-72 hour reading date to fall on a weekend or holiday unless a specific plan has been established to permit a reliable reading.
  - Interpretation:
    - Skin tests should be read by a SHD clinician at 48-72 hours after administration with the result recorded in double digits (e.g., 07 mm).
    - Skin tests may be read up to 96 hours under the following limited circumstances:
      - Reasonable efforts to read by 72 hours have failed.
      - The observed result is clearly 00 mm induration without any erythema or is clearly 10 mm induration or greater.
    - Classification of the skin-test result is pursuant to CDC guidelines set forth in *Core Curriculum on Tuberculosis: What the Clinician Should Know; 2000; 4th Edition and the table set forth in Appendix A.*
    - A skin test conversion is defined as the following: a documented increase of 10 mm induration (or greater) over the preceding 24 months (e.g., 08---≥18 mm or 00----≥10 mm). Such persons should be considered "PPD-positive," regardless of their placement in the risk matrix above.
    - Persons entering a serial TB skin testing program should undergo two-step testing at baseline. Specifically, if the initial result is negative AND no documented result from the preceding 12 months is available, a second PPD should be applied 1-3 weeks after the first. This second step should be interpreted using the same criteria as the first. For instance, if the first step is 08 mm and the second step is 16 mm, the second test is interpreted as "positive" (even though it is not a 10 mm increase).

II. Standing Orders for Obtaining Radiographic Studies of the Chest

- Indications
  - ♦ New positive skin test
  - ♦ Past Positive skin test with no chest radiograph since skin-test positivity was first documented
  - ♦ Skin test negative household contacts of pulmonary cases, if contact is:
    - under 15 years of age, or
    - HIV infected, or
    - immunocompromised
  - ♦ Reports of any abnormality on immigration chest radiographs
  - ♦ Persons seeking treatment for latent TB infection whose last chest radiograph is >3 months old or unavailable
  - ♦ Persons with a productive cough greater than 3 weeks in duration
  - ♦ End-of-therapy for active TB that included a pulmonary, pleural, or other intrathoracic component (e.g., hilar or mediastinal lymphadenopathy).
  - ♦ As otherwise directed by TB medical consultant

  Note: Patients undergoing administrative screening (e.g., for health care work) who have a history of both a previous positive skin test AND a subsequent normal chest radiograph should be referred to the provider who conducted these examinations for the appropriate documentation to provide to their employer. These patients may be invited to return with this documentation for consideration of treatment of latent infection if they are interested in treatment and do not have access to a primary care provider. If such documentation is not recoverable, the skin test and/or chest radiograph may be repeated when program or client resources permit.

- Chest-radiography should include both a posteroanterior and lateral view in the following settings:
  - ♦ Persons less than 10 years of age
  - ♦ HIV infection
  - ♦ Suspected or reported pleural effusion or hilar adenopathy
  - ♦ TB medical consultant direction

  Otherwise, chest radiography should be limited to a single, PA view.

- Interpretation
  - ♦ The TB medical consultant should review radiographs if a patient will be treated or is being treated directly by SHD, regardless of whether the radiograph has been previously reviewed by another health care provider. When time, distance, or access considerations provide a substantial barrier to obtaining the radiograph for viewing in a timely fashion (e.g., ≤2 weeks), a copy of the radiologist's report may be submitted to the TB medical consultant for review.
  - ♦ SHD nursing staff may accept the readings of outside health care providers for the purposes of making recommendations on treatment to community-based providers, provided that they make it clear to the consulting provider that SHD has not directly reviewed the image but has only seen the report.

III. Standing Orders for Sputum Evaluation

- Indications for Sputum Collection for Acid-fast Bacilli Smear and Culture
  - ♦ As part of screening for HIV-infected patients who are potential candidates for treatment of latent TB infection.
  - ♦ Among suspected and confirmed cases of active pulmonary TB:
    - Three baseline specimens, then
    - One-to-two specimens weekly until smear negative, then
    - Two specimens monthly until culture negative, then
    - Two specimens every three months until the end of therapy
  - ♦ Class B immigrants whose documentation of overseas screening indicates findings suggestive of active or inactive TB (e.g., "infiltrate", "fibrosis", "previous treatment").
  - ♦ As otherwise ordered by the TB medical consultant

- General procedure for collection of sputum specimens
  - Attempt to collect three specimens, unless otherwise directed by medical consultant
  - Five milliliters (5 ml) of sputum (not saliva) is the desired specimen.
  - In general, specimens should be collected upon rising in the morning, before the first meal.
  - If the patient has a productive cough, attempt to collect the first specimen while s/he is still in the clinic. Use the isolation room.
  - If the patient is unable to raise early morning sputum, suggest that s/he take a hot shower in a steamy room first. If that still fails, notify the medical consultant.

IV. Assignment of TB Diagnosis Classification and General Approaches to Treatment

Class 0: Not recently exposed, not infected (or exposed >3 months ago and infection ruled out with follow-up skin testing)
Class 1: Recently exposed, not infected (should become reclassified within 3 months after follow-up skin-testing)
Class 2: Latent infection
Class 3: Confirmed active disease
Class 4: Old, inactive disease
Class 5: Suspected active disease

- The TB medical consultant assign disease classification.
- The TB medical consultant will order all treatment.
- Management of class 1, 3, and 5 patients will be individualized but typically will reflect guidelines set forth by the American Thoracic Society and CDC.

- Physical examination in children <13 years of age
  At or subsequent to the time of PPD placement, a documented physical examination by a primary care or appropriately licensed SHD provider should be performed on all children <13 years of age, or in other circumstances as needed, to rule out signs of active tuberculosis (i.e., examination of heart, lungs, abdomen, peripheral lymph nodes, and skin) prior to initiating therapy for latent TB.

V. General Standing Orders for TB Therapy:

- In the context of treatment for latent infection or inactive disease, the choice of daily self-administered vs. twice weekly observed is delegated to the nursing staff. The following patients should be prioritized for twice-weekly observed therapy over patients who lack these characteristics:
  - ♦ Recent close contacts of pulmonary cases
  - ♦ HIV infection
  - ♦ Old, inactive TB (class 4)
  - ♦ Previous history of non-adherence to treatment
  - ♦ Homelessness
  - ♦ Chemical dependency
  - ♦ Severe mental health disorders (e.g., poorly controlled psychotic illnesses)
  - ♦ Frequent or recent incarceration
  - ♦ Patients with complex medical problems or taking multiple medications
  - ♦ Patients with considerable language and cultural barriers to adherence
  - ♦ Other patients whose social, medical, or behavioral circumstances raise reasonable concern about adherence.

- Suspected (Class 5) and confirmed (Class 3) active TB

  - ♦ Treatment regimen will be individualized and ordered by the TB medical consultant
  - ♦ As a local standard of medical and public health management, all active cases should receive treatment under direct observation. At nurse discretion, this may include use of videophone or analogous technology. Exceptions will be permitted only rarely. In cases where this is not the method of supervision, the alternative method of supervision (e.g., monthly or weekly pill counts, use of DOT extenders) and circumstances leading to its choice (e.g., provider refusal, schedule conflicts) should be clearly documented in the chart and reviewed with the TB medical consultant.

- For patients on "daily DOT", administration of medication should occur five times weekly, Monday-Friday (holidays excepted). Unless otherwise specified by the medical consultant, medications will not be administered or released to patients on weekends or holidays.

- Pyridoxine (25 mg po daily or 50 mg po twice weekly) should be routinely administered to the following patients receiving isoniazid, regardless of whether or not the TB medical consultant has ordered it:
  - ♦ Underlying neuropathy
  - ♦ Regimen includes other agents in addition to isoniazid
  - ♦ Diabetes mellitus
  - ♦ HIV infection

- Seizure disorder, anti-seizure medication, anti-psychotic medication, or other conditions associated with lowered seizure threshold
- Conditions associated with chronic malabsorption
- Chronic renal failure
- Alcoholism
- Pregnancy
- Weight <90% of ideal
- Age >65

- Completion of Therapy for Active Disease

  - Appendix B shows, under typical circumstances, when the medical consultant will consider a patient's therapy complete.

  - Duration of treatment may be extended by the medical consultant in the following circumstances:
    - Cavitary or otherwise extensive disease
    - Culture conversion delayed beyond two months into therapy
    - Other clinical judgment that extended therapy is warranted

  - Duration of alternative regimens not listed here will be individualized.

  - Each case's completion of therapy should be reviewed and approved by the medical consultant before discontinution of treatment occurs.

- Lapses in Treatment and Completion of Therapy for Latent or Inactive TB:

  - Appendix C shows when clinical staff can consider a patient's therapy complete

  - Continue current therapy in dose and frequency as previously ordered and seek TB medical consultant consultation if

    - lapses in therapy of greater than 3 weeks (cumulatively) occurred during the first three months of therapy, OR

    - other factors lead to a desire for medical consultation regarding adequacy of therapy

- Indications for repeat chest radiograph in patients who have lapsed or failed to start treatment
  - Under treatment for active TB
  - Symptoms of TB
  - Intercurrent illness with productive cough lasting ≥2 weeks

- Lapse greater than three months (since last dose or, if never started, since last chest radiograph)
- Intercurrent delivery of an infant

VI. Standing Orders for Drug Dosing:

- When the TB medical consultant orders drugs to be dosed "per standing orders," use the tables in Appendix D to administer correct doses of medications. Verbal or written orders from the TB medical consultant always supersede these standing orders.
- Weigh all active case and children <13 years on a monthly basis. Other patients should be weighed every three months. Adjust dose per tables, if necessary. However, if a *reduction* in weight would result in a decreased dose, hold the dose at its current level and refer the chart to the TB medical consultant.
- Seek TB medical consultant consultation if standing order doses conflict with nursing judgment in the case at hand or if patient weight falls outside parameters set forth in tables.

- **Standing Orders for HIV Counseling and Testing**

  - All suspected and confirmed active cases should be strongly encouraged to undergo HIV counseling and testing, unless the patient is already known to be HIV infected. Highest priority should be placed on persons who:
    - are aged 25-54 years, OR
    - homeless, OR
    - have a history of drug injection

  - Patients undergoing screening or treatment for LTBI should be assessed for risk of HIV infection, with highest priority for this assessment being directed to homeless persons and close contacts of active cases.
    - Individuals with risk factors for HIV infection… (for example
      - drug injection
      - male-male sexual contact
      - partner HIV infected
      - partner injecting drugs
      - multiple partners in preceding 3 months
      - sexually transmitted disease in preceding year

      …who have not been tested in the preceding 12 months should be encouraged to undergo HIV counseling and testing.

    - Other persons without risk factors undergoing LTBI screening may be offered HIV counseling and testing at the TB nurse's discretion.

VIII. Standing Orders for Monitoring Adverse Effects to and Tolerance of Treatment:

- Patients should be clinically evaluated for adherence, tolerance, and adverse effects on the following schedule:

Regimen	Clinical Evaluation	Laboratory Evaluation
INH or RIF for Class 2 or 4	Baseline, monthly and prn ▪ Anorexia ▪ Nausea ▪ Vomiting ▪ Abdominal pain ▪ Jaundice ▪ Fever ▪ Headache ▪ Fatigue ▪ Joint pains ▪ Paraesthesiae ▪ Rash	Hepatic function panel (HFP) at baseline if: Ongoing drug injection Ongoing alcohol use ≥10 drinks per week Chronic hepatitis Other liver disease Multiple medications Pregnancy Clinical suspicion of underlying liver disease Otherwise ordered by medical consultant In these patients, the plan for follow-up biochemical and viral serology testing, if any, will be individualized through TB medical consultant consultation and physician orders. Otherwise, HFP should only be conducted as ordered by TB medical consultant or as clinically indicated by patient report of symptoms of hepatitis
RIF/PZA	Baseline and 2, 4 , 6 and 8 weeks and prn ▪ Same content as for INH or RIF monotherapy, but also include assessment for easy bruising or bleeding gums, blood in stools or urine	HFP at baseline, 2, 4, and 6 weeks. Otherwise, HFP should only be conducted as ordered by TB medical consultant or as clinically indicated by patient report of symptoms of hepatitis.
Other treatment regimens (e.g., multiple medications for)	Baseline, monthly and prn ▪ Same content as above, plus visual acuity and color discrimination check at baseline. ▪ Vision assessments thereafter need only be repreated prn or if EMB is extended beyond two months.	Comprehensive metabolic panel (CMP) and complete blood count with platelets and differential (CBC) at baseline. The plan for follow-up laboratory testing, if any, will be individualized through TB medical consultant consultation and physician orders.

- Patients should be educated about the adverse effects of TB medications and told to hold their medications and call the clinic immediately if such effects develop.
  - ♦ Hepatotoxicity (isoniazid, rifampin, pyrazinamide, ethionamide): nausea, vomiting, right upper quadrant pain, anorexia, jaundice, bilirubinuria, acholic stools
  - ♦ Gastritis (pyrazinamide, rifampin, fluoroquinolones, para-amino salicylate): severe epigastric pain, nausea, vomiting
  - ♦ Hypersensitivity (any): rash, fever

- ♦ Neurologic (isoniazid, ethionamide): headache (severe, persistent), paraesthesiae
- ♦ Visual (ethambutol, isoniazid, ethionamide): visual changes (loss of acuity, loss of color discrimination
- ♦ Vestibular (aminoglycosides and capreomycin): tinnitus, loss of hearing, vertigo, loss of balance
- ♦ Joints (pyrazinamide, fluoroquinolones, isoniazid): gout, arthralgias
- ♦ Muscles (fluoroquinolones): tendon pain or rupture
- ♦ Hematologic (rifampin): easy bruising, bleeding gums, blood in stools or urine

- Among women of potentially childbearing age (13-54 years) women, assess last menstrual period and perceived pregnancy status monthly. If pregnancy is suspected (e.g., menses overdue), perform urine HCG and refer to TB medical consultant if positive.

- Subject to nurse discretion, monthly monitoring of persons undergoing treatment for latent infection may be done by telephone, unless clients require specimen collection for laboratory evaluation or unless other elements in the patient's social, medical, or behavioral circumstances make such history-taking reasonably unlikely to be reliable.

- All patients with active disease must be seen in person at least monthly by SHD nursing staff or the community-based provider who is managing their TB disease.

- Administration or dispensing of medication should cease for any patient who is more than one month overdue for monitoring.

  - ♦ If the patient has active TB, the chart should be referred to the TB Control Officer for remedy.

  - ♦ If the patient has latent or inactive TB, then the chart should be held open for up to one additional month (two months total) before dismissing the case and closing the file.

  - ♦ Prior to such closure, at least two telephone attempts and one written (certified mail) attempt to engage the patient should be conducted and documented in the chart.

VIII. Standing Orders for Notification of TB Medical Consultant:

- Immediate--hold medications (if applicable) and immediately contact TB medical consultant by telephone:
  - ♦ Icterus
  - ♦ Severe nausea and vomiting (e.g., ≥2 times per day for ≥ 3 days)
  - ♦ Other overt clinical evidence of hepatitis
  - ♦ Transaminases >5 times upper limit of normal (e.g., >200 IU/ml)
  - ♦ Transaminases >2 times upper limit of normal (e.g., >80 IU/ML) and symptoms consistent with hepatitis
  - ♦ Other critical laboratory abnormalities (e.g., platelets <50K, WBC<2500/ul)
  - ♦ Gout
  - ♦ Tendon pain or rupture (if on fluoroquinolones)
  - ♦ Overt bleeding manifestations (e.g., purpura, petechiae, bleeding gums, hemorrhage)
  - ♦ Anaphylactic or anaphylactoid reaction reported
  - ♦ Hospitalization due to TB medications in latent infection
  - ♦ Hospitalization for any reason among active cases

- Priority—hold medications (if applicable) and refer chart (or fax key contents) to TB medical consultant for review and feedback within 48 hours:
  - ♦ New suspected case (mail radiographs and key chart contents)
  - ♦ Persistent, severe headache
  - ♦ Persistent nausea and vomiting to a degree less than set forth above under "Immediate"
  - ♦ Paraesthesiae
  - ♦ Non-urticarial rash
  - ♦ Visual changes
  - ♦ Vestibular changes
  - ♦ Other adverse effect symptoms not of an emergent nature which still merit prompt attention
  - ♦ Hospitalization for reasons unrelated to TB or TB treatment among persons with latent infection

- Routine—continue medications and refer chart (or fax key contents) to TB medical consultant for review and feedback within 96 hours
  - ♦ Transaminases > upper limit of normal (e.g., >40 IU/ml), but not meeting more urgent criteria set forth above
  - ♦ Other (non-critical) laboratory abnormalities
  - ♦ Pruritus without rash
  - ♦ Other adverse effect symptoms not of an urgent nature

- Other—hold for next on-site visit by (or courier shipment to) TB medical consultant

- Charts and radiographs of asymptomatic persons with positive skin tests and radiographs completed.
- Charts and radiographs of patients awaiting diagnostic classification whose sputum cultures are negative and final .
- Charts of patients on treatment for active disease must be reviewed by the TB medical consultant at least every month and again prior to dismissal.

IX. Contact Investigations

- Contact investigations should be individualized by the TB public health nurse/case manager in consultation with the TB medical consultant. The following general guidelines should be taken into consideration.

- Household contacts are defined as persons who live or have recently lived in the same residence as the TB case or who spend or have recently spent more than several hours per day in the case's residence on several days each week.

- "Analogous" contacts are defined as other persons sharing closed air space several hours per day several days per week.

- Pulmonary cases:
  - ♦ All household and analogous contacts should have a symptom check, medical history, and PPD. Skin testing can be deferred for contacts with a documented previous positive test. In addition, a chest radiograph should be performed if the contact is
    - PPD positive (i.e., ≥05 mm), or
    - under 15 years of age, or
    - HIV infected, or
    - immunocompromised

    - Those with negative skin tests (<05 mm), should have a repeat skin test applied 12 weeks after contact with the infectious case was broken (either by isolation or cessation of infectiousness following initiation of therapy).
    - In most cases, the TB medical consultant will initiate treatment for latent TB infection among children (especially those <5 years of age) and immunocompromised contacts, pending the outcome of the second skin test. Detection of any induration among such contacts during the first or second round of skin testing is cause for seeking TB medical consultation.

  - ♦ Additional investigation and testing in work, leisure, health care and other environments should be managed on a case-by-case basis in consultation with the TB medical consultant and taking into account the results already obtained from those at highest risk of transmission.

- Extrapulmonary cases:
  - ♦ No specific contact investigation is necessary, but household and analogous long-term contacts should be referred to their primary care provider or SHD for skin testing.
  - ♦ At nurse discretion, more comprehensive contact follow-up may be performed as resources permit.

- Pediatric cases:

- ♦ When active TB (either pulmonary or extrapulmonary) is found in a child <5 years of age, efforts should be taken to identify an infectious case in the child's environment.
- ♦ In most cases this will include symptom check, medical history, PPD, *and* chest radiograph for household contacts, extended family members with frequent contact, and other analogous contacts.
- ♦ Pursuit of a source case beyond these groups should be pursued only after discussion with the TB medical consultant.

- Management of infants born to mothers with active TB disease: refer to TB medical consultant for direction.

- Other close contacts under 6 months of age: refer to TB medical consultant for direction.